CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: July 6, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Anterior Diskectomy with Fusion and Plating at C4-C7 with one (1) day length of stay (LOS)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This physician is Board Certified in Neurological Surgery with over 16 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☐ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

04/01/04: Clinical Evaluation by MD (lumbar spine)

04/29/04: MRI of the Lumbar Spine

05/06/04: Follow-up Note by MD (lumbar spine)

10/11/04: Follow-up Note by MD (lumbar spine)

10/18/04: Follow-up Note by MD (lumbar spine)

11/08/04: Follow-up Note by MD (lumbar spine)

12/09/04: Follow-up Note by MD (lumbar spine)

01/13/05: Follow-up Note by MD (lumbar spine)

02/25/05: Follow-up Note by MD (lumbar spine)

05/12/05: Follow-up Note by MD (lumbar spine)

07/14/05: Follow-up Note by MD (lumbar spine)

08/04/05: Lumbar Spine – Two Views Flexion and Extension interpreted by MD

08/04/05: MRI Lumbar Spine interpreted by MD

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08/08/05: Follow-up Note by MD (lumbar spine)
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08/16/05: History and Physical Examination by MD with Hospital (lumbar spine)

08/16/05: Operative Report by MD (lumbar spine)

08/16/05: Lumbar Spine Series interpreted by MD

09/15/05: Follow-up Note by MD (lumbar spine)

09/15/05: Two Views Lumbar Spine interpreted by MD

11/21/05: Spine Lumbo-Sacral 2-3 Views interpreted by MD

11/21/05: Follow-up Note by MD (lumbar spine)

01/16/06: Spine Lumbo-Sacral 2-3 Views interpreted by MD

01/16/06: Follow-up Note by MD (lumbar spine)

02/01/06: MRI Lumbar Spine interpreted by MD

02/27/06: Follow-up Note by MD (lumbar spine)

03/28/06: Lumbar Myelogram performed by MD and interpreted by MD

03/28/06: CT Scan Lumbar Spine interpreted by MD

04/03/06: Follow-up Note by MD (lumbar spine)

05/01/06: Follow-up Note by MD (lumbar spine)

08/25/06: Operative Report by MD (Lumbar ESI)

02/13/12: Follow-up Note by MD

03/08/12: MRI Cervical Spine interpreted by MD

03/19/12: Follow-up Note by MD

05/03/12: Follow-up Note by MD (lumbar spine)

05/07/12: Follow-up Note by MD 05/14/12: UR performed by MD 05/30/12: UR performed by MD

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx while working. He was involved in a head-on collision with a sudden onset of very severe neck pain and bilateral shoulder and arm pain. According to Dr. notes, he was seen in the ER and x-rays were taken that showed no fracture or dislocation. He was released from ER and since the injury has had increasingly severe posterior cervical and interscapular pain with posterior muscle contraction headaches and radicular pain into both shoulders, and arms, mainly on the left side, along with a feeling of some numbness and dysesthesias. He has had no specific treatment for the cervical spine. He was treated by Dr. for a severe post-traumatic lumbar disk problem unrelated to the cervical injury. On August 16, 2005, the claimant underwent a Decompressive L4-5 Laminectomy and Fusion by MD for the unrelated injury.

On February 12, 2012, the claimant was evaluated by, MD for the increasing cervical pain. X-rays were reported to show very severe disease at C5-6 with total collapse of the disk space with significant foraminal impingement with slightly lesser disease at C6-7. On physical examination, neck extension and bilateral bending reproduced pain into both shoulders and arms. There was mild Lhermitte phenomenon with range of motion of the neck. He tended to keep his head and neck slightly flexed. There was a loss of cervical lordosis and he had paracervical muscular tightness. He had an essentially frozen left shoulder with significant weakness of the left deltoid. Deep tendon reflexes were trace in the biceps and

triceps bilaterally. Biceps and triceps weakness was noted, particularly on the left side. There was decreased sensation in the bilateral C6 and C7 dermatomes, particularly left C6. Adson's maneuver was negative bilaterally. Diagnosis: Severe post-traumatic C5-6 and C6-7 disk pathology with a chronic mechanical cervical syndrome and cervical radiculopathies with possible early myelopathy. A cervical MRI scan was recommended.

On March 8, 2012, MRI of the Cervical Spine, Impression: C3-4: Mild disk osteophyte complex narrows the anterior subarachnoid space. No focal disk protrusion, cord contact or central spinal stenosis. There is some uncinate hypertrophy and facet disease with mild left neural foraminal narrowing, the right grossly patent at C3-4. C4-C5: Broad-based disk osteophyte complex with a more focal disk protrusion which is central and just to the left of midline causing cord contact and ventral effacement of the cord, but no signal abnormality in the cord. There is central spinal stenosis. Uncinate hypertrophy and facet hypertrophic degenerative change with mild left and moderate right neural foraminal stenosis at C4-5. C5-C6: Prominent broad-based disk osteophyte complex causes cord contact and ventral effacement of the cord. There is central spinal stenosis but no signal abnormality in the cord. Uncinate hypertrophy and facet hypertrophic degenerative change with severe bilateral neural foraminal stenosis which may be worse on the right at C5-6. C6-7: Prominent disk osteophyte complex which may be a little asymmetric in the left paramedian location causes cord contact, but no significant cord deformity. There is some central spinal stenosis. Uncinate hypertrophy and facet disease with mild/moderate right and severe left neural foraminal stenosis at C6-7. C7-T1: Mild disk osteophyte complex. No focal disk protrusion or central spinal stenosis. There is mild bilateral neural foraminal narrowing a little worse on the left.

On March 19, 2012, the claimant was re-evaluated by MD who reviewed the MRI and recommended an anterior diskectomy, interbody fusion, and plating at all three levels.

On May 7, 2012, the claimant was re-evaluated by MD who reported the claimant cervical problem had gotten much worse over the years and he now had a myeloradiculopathy with numbness and weakness in all four extremities in addition to the bilateral radicular shoulder and arm pain. Any neck extension and bilateral bending reproduced pain down both arms. The claimant was reported to have depressed upper extremity reflexes. He had several beats of ankle clonus and a weak Babinski response with a somewhat wide-based gait. The claimant wanted to proceed with the recommended anterior diskectomy, interbody fusion and plating from C4 through C7.

On May 14, 2012, MD performed a UR on the claimant. Rationale for Denial: The injured worker does not meet the guidelines. We do not have past records to know what his neurologic exam findings were over the past 10 years. None of the current findings are really diagnostic. The reflexes are symmetrical, motor power is minimally changed and symmetrical. Sensory findings are minimally described

and not well localized. No EMG is presented. The MRI changes are all degenerative and no apparent cord changes and only degenerative foraminal narrowing. There is no clear mechanical character to his continuous pain. Therefore the medical necessity of the requested procedure was not established.

On May 30, 2012, MD performed a UR on the claimant. Rationale for Denial: On 3/8/12, the claimant underwent an MRI of the cervical spine which noted degenerative disc disease (DDD) with foraminal stenosis and spondylotic changes at multiple levels; there was no traumatic pathology identified. There is not a comprehensive physical or neurological evaluation. There is not a detailed evaluation of the claimant's symptomatology. The claimant's reflexes are symmetrical, sensory findings are minimal and not localized. There is no EMG within the documentation and the MRI notes degenerative changes only. There is no traumatic pathology that would support the need of this type of surgery. Therefore, I agree with the previous peer reviewer and uphold the denial.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The previous adverse determinations are upheld. The claimant's history is concerning for cervical trauma with radiculopathy at time of injury on xx/xx/xx. He only had cervical x-rays in 2002 according to the records as no MRI or CT myelogram from 2002 is noted. There is a lack of any discussion of his cervical and arm symptoms until 2/12/2012 with no intervening history on whether he had physical therapy, or cervical injections for ongoing neck or arm symptoms. His physical exam suggests C5, C6 and C7 radiculopathy as well as myelopathy. His Cervical MRI on 3/8/12 does mention disc herniation/osteophytes at C5/6 and C6/7 with the herniations possibly traumatic. The lack of a prior Cervical MRI or CT myelogram to compare to the March 2012 study makes any definitive statement about the disc herniations impossible. The ODG guidelines make the EMG optional in the presence of radicular and reflex findings or a Spurling's sign which the claimant's Lhermite sign suggests. This surgical request would have to be denied at this time because the lack of data from 2002 to 2012 suggesting these MRI findings are due to degenerative cervical changes unless they were present on a cervical MRI soon after his injury in xx. The claimant should pursue surgery through some other source as his symptoms suggest a severe myelopathy. It is hard to tie his present symptoms to an injury 10 years ago without better clinical records from the intervening time and therefore, the request for Anterior Diskectomy with Fusion and Plating at C4-C7 with one (1) day length of stay (LOS) is denied. Per ODG:

<u>ODG Indications for Surgery</u>™ -- Discectomy/laminectomy (excluding fractures):

Washington State has published guidelines for cervical surgery for the entrapment of a single nerve root and/or multiple nerve roots. (Washington, 2004) Their recommendations require the presence of all of the following criteria prior to surgery for each nerve root that has been planned for intervention (but ODG does not agree with the EMG requirement):

A. There must be evidence of radicular pain and sensory symptoms in a cervical distribution that correlate with the involved cervical level or presence of a positive Spurling test.

- B. There should be evidence of motor deficit or reflex changes or positive EMG findings that correlate with the cervical level. *Note:* Despite what the Washington State guidelines say, ODG recommends that EMG is optional if there is other evidence of motor deficit or reflex changes. EMG is useful in cases where clinical findings are unclear, there is a discrepancy in imaging, or to identify other etiologies of symptoms such as metabolic (diabetes/thyroid) or peripheral pathology (such as carpal tunnel). For more information, see EMG.
- C. An abnormal imaging (CT/myelogram and/or MRI) study must show positive findings that correlate with nerve root involvement that is found with the previous objective physical and/or diagnostic findings. If there is no evidence of sensory, motor, reflex or EMG changes, confirmatory selective nerve root blocks may be substituted if these blocks correlate with the imaging study. The block should produce pain in the abnormal nerve root and provide at least 75% pain relief for the duration of the local anesthetic.
- D. Etiologies of pain such as metabolic sources (diabetes/thyroid disease) non-structural radiculopathies (inflammatory, malignant or motor neuron disease), and/or peripheral sources (carpal tunnel syndrome) should be addressed prior to cervical surgical procedures.
- E. There must be evidence that the patient has received and failed at least a 6-8 week trial of conservative care.

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

Fusion, anterior cervical

Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminoplasty.) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. (Bertalanffy, 1988) (Savolainen, 1998) (Donaldson, 2002) (Rosenorn, 1983) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. (Bambakidis, 2005) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Savolainen, 1998) (Dowd, 1999) (Colorado, 2001) (Fouyas-Cochrane, 2002) (Goffin, 2003) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. (Wieser, 2007) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

- (1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute: Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. (Jacobs-Cochrane, 2004) (Abd-Alrahman, 1999) (Dowd, 1999) (Martins, 1976) (van den Bent, 1996) (Savolainen, 1998) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. (Ragab, 2006) (Eck, 2002) (Matsunaga, 1999) (Katsuura, 2001) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. (Yamamoto, 1991) (Abd-Alrahman, 1999)
- (2) Fusion with autograft versus allograft: The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). (<u>Jacobs-Cochrane</u>, 2004) (<u>McConnell</u>, 2003) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (<u>Younger</u>, 1989) (<u>Sawin</u>, 1998) (<u>Sasso</u>, 2005) Autograft is thought to increase fusion rates with less graft collapse. (<u>Deutsch</u>, 2007). See <u>Decompression</u>, myelopathy.
- (3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level: A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients. (Samartzis, 2005)

- (4) Fusion with different types of autograft: The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. (McGuire, 1994)
- (5) Fusion with autograft versus fusion with autograft and additional instrumentation:

Plate Fixation: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. (Wright, 2007) See Plate fixation, cervical spine surgery.

Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). (Poelsson, 2007) (Varuch, 2002) (Hacker 2000) See also Adjacent segment disease/degeneration (fusion).

(6) Fusion with allograft alone versus with allograft and additional instrumentation:

Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. (Kaiser, 2002) (Martin, 1999) See Plate fixation, cervical spine surgery. *Complications:*

Collapse of the grafted bone and loss of cervical lordosis: collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. (Troyanovich, 2002) (Herrmann, 2004) (Katsuura, 1996) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. (Peolsson, 2004) (Haden, 2005) (Poelsson, 2007) (Hwang, 2007) Pseudoarthrosis: This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. (Kuhns, 2005) (Mummaneni, 2004) (Coric, 1997)

Anterior versus posterior fusion: In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007) Predictors of outcome of ACDF: Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health, litigation and workers' compensation. (Anderson, 2009) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008)

See <u>Plate fixation</u>, <u>cervical spine surgery</u>. See also <u>Adjacent segment disease/degeneration</u> (fusion) & <u>Iliac crest donor-site pain treatment</u>.

Use of Bone-morphogenetic protein (BMP): FDA informed healthcare professionals of reports of lifethreatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. (FDA MedWatch, 2008) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher

rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). (Cahill-JAMA, 2009)

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

ODG hospital length of stay (LOS) guidelines: **Discectomy/ Corpectomy** (icd 80.51 - Excision of intervertebral disc) Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) \$26,219 Best practice target (no complications) -- 1 day **Laminectomy** (icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root) Actual data -- median 2 days; mean 3.5 days (±0.1); discharges 100,600; charges (mean) \$34,978 Best practice target (no complications) -- 1 day **Cervical Fusion, Anterior** (81.02 -- Other cervical fusion, anterior technique) Actual data -- median 1 day; mean 2.2 days (±0.1); discharges 161,761; charges (mean) \$50,653 Best practice target (no complications) -- 1 days **Cervical Fusion, Posterior** (81.03 -- Other cervical fusion, posterior technique) Actual data -- median 4 days; mean 5.7 days (±0.2); discharges 16,852; charges (mean) \$97,781 Best practice target (no complications) -- 4 days **Craniocervical Atlas-Axis Fusion** (81.01 -- Atlas-axis spinal fusion) Actual data -- median 5 days; mean 7.8 days (±0.3); discharges 2,966; charges (mean) \$117,838 Best practice target (no complications) -- 5 days

IRO REVIEWER REPORT TEMPLATE -WC

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:
☐ ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL &
ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
GUIDELINES
☐ DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR
GUIDELINES
■ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW
BACK PAIN
☐ INTERQUAL CRITERIA
☐ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN
ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
☐ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
MILLIMAN CARE GUIDELINES
ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE &
PRACTICE PARAMETERS
☐ TEXAS TACADA GUIDELINES
☐ TMF SCREENING CRITERIA MANUAL
PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE
(PROVIDE A DESCRIPTION)
OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)LHL602. 7